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Applicant(s): Badley et al.

Application No.: 09/554,956

Filed: 7/11/2000

Title: Improvements in or Relating to
Displacement Assays

Attorney Docket No.: IMIN.P-019

Group Art Unit: G Gabel

Examiner: 1641

OFFICIAL

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450RESPONSE TO OFFICIAL ACTION

Dear Sir:

This is in response to the Official Action mailed November 3, 2003 for the above-captioned application. Applicants request an extension of time sufficient to make this paper timely, and enclose the fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

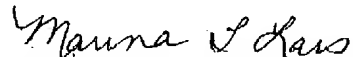
Reconsideration of the application is respectfully requested.

Applicants thank Examiner Gabel for taking the time to meet with their attorney to discuss this case. This paper will serve as Applicants' summary of that interview.

Claims 1-3, 5-16 and 22 are pending and under examination.

On the merits, the Examiner has rejected claims 1-3, 7-10 and 13-16 as anticipated by Schramm et al., US Patent No. 5,281,539. For there to be anticipation, the reference must teach each and every element of the claimed invention. In rejecting the claims, the Examiner has

I hereby certify that this paper and any attachments named herein are transmitted to the United States Patent and Trademark Office, Fax number: (571) 273-0820 on March 3, 2004.



Marina T. Larson, PTO Reg. No. 32,038

March 3, 2004

Date of Signature

pointed in particular to Fig. 7 of Schramm, but has not specifically said how this teaching meets the limitations of the claims. As discussed at the interview, Fig. 7 of Schramm '539 shows a first surface (Sensor 1) that has a displaceable moiety bound to it. There is also a second surface (Sensor 2) that captures the displaceable moiety when it has been displaced from Sensor 1 in the presence of analyte. It is at that point that any similarity between the claimed invention and the Schramm '539 reference, to the extent the reference can be understood, ends.

Claim 1 requires that the capture of the displaceable moiety on the second surface generate a species capable of producing a detectable signal. The Examiner has not said how the captured moiety binding to Sensor 2 in Schramm '539 meets this limitation. In particular, in the embodiment described in Fig. 7, the sensors are said to be Clark electrodes. Clark electrodes are oxygen electrodes,¹ and they would not directly detect anything that is bound to the sensor surface. As was mentioned at the interview, it is not apparent that the embodiment of Fig. 7 of Schramm '539 is enabling, since there is no description of how a signal is generated in this system, and how the signal depends on the binding of the displaceable moiety to surface of Sensor 2. Thus, it is not clear how this disclosure meets the limitation of claim 1 which states that the signal "cannot be generated unless and until the displaceable moiety is captured on the second surface," since it is not clear how a signal is generated.

During the interview, the Examiner and Applicants attorney also discussed support for the terminology in the claims that the signal "cannot be generated unless and until the displaceable moiety is captured on the second surface." It was pointed out that this language is supported on Page 6, lines 18-20.

¹ As defined on one web site, a Clark electrode is "An oxygen electrode consisting of the tip of a platinum wire exposed to a thin film of electrolyte covered by a plastic membrane permeable to oxygen but not to water or the electrolyte. When a certain voltage is applied, oxygen is destroyed at the platinum surface; the flow of current is then proportional to the rate at which oxygen can diffuse to the platinum surface from the gas or liquid sample outside the membrane, and is thus a measure of the oxygen pressure in the sample; commonly used to measure oxygen pressure in arterial blood samples." <http://www.books.md/C/dic/Clarkelectrode.php>

Furthermore, claim 1 of the present application requires the step of "treating the specific capable of generating a detectable signal to generate said signal." "Treating" in this case means the application of some stimulus that results in the generation of a signal. As reflected in the specification, treatment may be in the form of an evanescent or acoustic wave (Page 7, lines 10-15), or an application of current or potential to allow monitoring of an electrochemical property (Page 8, lines 7-16; Page 24, line 24 shows use of an applied voltage).

The Examiner has not indicated what teaching in Schramm '539 corresponds to this step, and given the inadequacy of Schramm's disclosure on the functioning of the apparatus of Fig. 7, no assumptions about its operation should be made.

For these reasons, Applicants submit that the rejection should be withdrawn.

Claim 11 stands rejected over the combination of Schramm '539 in view of Partin '630. It is noted that the Examiner states that this is a 102(b) rejection, but from the context it is assumed that a rejection under §103 was intended. The Examiner relies on the same characterization of Schramm '539 and asserts that because of Partin it would have been obvious to use the waveguide as taught by Partin to detect the signal. This argument raises several issues. First, as discussed above, the portion of Schramm '539 that the Examiner relies upon does not in fact disclose the limitations of the independent claim on which claim 11 depends. Furthermore, Applicants submit that the combination of references is improper. "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1986) (citing *ACS Hosp. Syss., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)). "[T]he factual inquiry whether to combine references must be thorough and searching." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001).

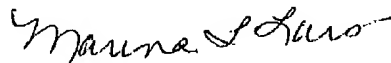
Here, the embodiment of Fig. 7 does not make use of a fluorescent or other optical indicator. It uses an electrode, although the manner of such use is not clearly disclosed. The mere fact that Schramm '539 discloses optical signaling in other embodiments does not stand as a suggestion to use them in the embodiment of Fig. 7, and then to modify these further to use the

waveguide of Partin in the process. Thus, as discussed at the interview, the rejection is in error for this additional reason and should be withdrawn.

Claims 5, 6 and 22 are rejected as obvious over the combination of Schramm '539 and Presta. This rejection assumes that the basic arguments concerning Schramm '539 are correct. Since this is not the case, this rejection should be withdrawn as well.

In view of the foregoing arguments, Applicants submit that all claims are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully Submitted,



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